K033229

12/17/03

BERNÀRD TECHNOLOGIES, INC.

[1] 510(k) Summary

[2] Bernàrd Technologies, Inc.
75 E. Wacker Dr.
Chicago, IL 60601

Contact: Michael D. Lelah, PhD
Telephone: 312-337-7007
Fax: 312-337-0505

October 1, 2003

[3] Trade Name: (Multiple labels) Powder-Free Vinyl Examination Gloves
Common Name: Powder-Free Vinyl Examination Gloves
Classification Name: Patient Examination Gloves, powder-free

[4] Legally marketed device to which equivalency is being claimed: Class II powder-free patient examination glove 80LYZ, that meets all of the requirements of ASTM standard D 5250-00.

[5] Device Description: Class II powder-free patient examination glove 80LYZ, that meets all of the requirements of ASTM standard D 5250-00.

[6] Intended Use: A powder-free patient examination glove is a disposable device made of synthetic material that may bear a trace amount of glove powder and is intended to be worn on the hand or finger(s) for medical purposes to provide a barrier against potentially infectious materials and other contaminants.

[7] Technological Characteristics:

Characteristics	Standard
Dimensions	Meets ASTM D 5250-00
Physical Properties	Meets ASTM D 5250-00
Freedom from Holes	Meets ASTM D 5250-00
Powder-Free	Meets ASTM D 5250-00

Biocompatibility:

Primary Skin Irritation in Rabbits	Passes
Repeated Patch Dermal Sensitization Test (Buehler)	Passes

Substantial Equivalence: Both in its intended use and/or physical characteristics, this device is equivalent to legally marketed vinyl powder-free gloves. Except for a plastisol ingredient, this device is substantially equivalent to legally marketed vinyl powder-free gloves.

[8] Performance Data: Leaching and biocompatibility comparative studies between this device and legally marketed powder-free gloves demonstrate that this device is substantially equivalent to legally marketed vinyl powder-free gloves.

[9] Clinical data not required.

[10] (Multiple labels) Powder-Free Vinyl Examination Gloves meet or exceed the ASTM standard. (Multiple labels) Powder-Free Vinyl Examination Gloves meet labeling claims and pinhole AQL from the Freedom from Holes data in [7] above.

[11] This summary will include any other standards, special controls, labeling, or regulatory information reasonably deemed necessary by the FDA.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2003

Mr. Michael D. Lelah, Ph.D.
Managing Director, gloves
Bernàrd Technologies, Incorporation
75 East Wacker Drive
Chicago, Illinois 60601

Re: K033229
Trade/Device Name: (Multiple Labels) Powder- Free Vinyl Examination Gloves
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYZ
Dated: October 1, 2003
Received: October 6, 2003

Dear Mr. Lelah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K033229

3.0 Indications for Use Statement:

INDICATIONS FOR USE

Applicant: Bernard Technologies, Inc.

510(k) Number: N.A.

Device Name: (Multiple labels) Powder-Free Vinyl Examination Gloves

Indications for Use: A powder-free patient examination glove is a disposable device made of synthetic material that may bear a trace amount of glove powder and is intended to be worn on the hand or finger(s) for medical purposes to provide a barrier against potentially infectious materials and other contaminants.

_____

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number:_____

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)